UNAIDS
QUESTIONS AND ANSWERS
5 August 1999

MOTHER-TO-CHILD TRANSMISSION (MTCT) OF HIV
Background Briefing

Q: How big is the problem of HIV infection in children?

Nearly 4.5 million children below the age of 15 years have been infected with HIV since the AIDS epidemic began, and more than 3 million of them have already died of AIDS. Today, on a global scale, children are becoming infected at about the rate of one child every minute of every day. In 1998, one in ten of all new infections was a child, and the vast majority of them acquired the virus from their infected mothers. Though Africa accounts for only 10% of the world's population, it is home to 90% of the world's HIV-infected children, largely as a consequence of high fertility rates combined with very high levels of HIV infection among women. However, the number of cases in India and South-East Asia appears to be rising rapidly.

Q: What are the consequences of such high levels of infection?

The effects of the epidemic among young children are serious and far-reaching. AIDS threatens to reverse years of steady progress in child survival achieved through such measures as the promotion of breastfeeding, immunisation and oral rehydration. UNAIDS believes that by the year 2010, AIDS may have increased mortality of children under 5 years of age by more than 100% in regions most affected by the virus. The trend is already clear. In Harare, Zimbabwe, for example, the death rate among infants in their first year of life increased from 30 to 60 per 1000 between 1990 and 1996. And deaths among one-to-five year olds, the age group in which the bulk of child AIDS deaths are concentrated, rose even more sharply -- from 8 to 20 per 1000 -- in the same period. In a growing number of countries, AIDS is now the biggest single cause of child death.

Q: How are these children becoming infected?

Mother-to-child transmission (MTCT) is by far the largest source of HIV infection in children below the age of 15 years. In countries where blood for transfusion and blood products are regularly screened, and where clean syringes and needles are widely available in health centres and hospitals, MTCT is virtually the only source of infection in young children. The extremely high rates of HIV infection among women of childbearing age in some parts of the world -- and the increasing risk of infection among women everywhere -- is therefore doubly concerning.

Q: What is the extent of HIV infection among women of childbearing age?

Currently, there are almost 14 million women of childbearing age throughout the world who are HIV positive. Among those women who are pregnant, the highest rates of infection have been reported from sub-Saharan Africa. In urban centres in southern Africa, for example, HIV rates of 20-30% among pregnant women tested anonymously at antenatal clinics are common. And rates above 40% have been recorded in Botswana and Zimbabwe. According to data from UNAIDS, there are very few places outside sub-Saharan Africa in which the prevalence of HIV infection among pregnant women has reached 10%, let alone the extremely high figures seen in this region. However, this is partly because the epidemic in other badly affected countries is younger and less advanced than in sub-Saharan Africa, so there is no room for complacency.

Figures from UNAIDS show that the risk of infection is increasing for women everywhere -- in developed and developing countries alike. In France, women's share of reported AIDS cases increased from 12% in 1985 to 20% ten years later. In Spain female AIDS cases rose from 7% to 19% of all AIDS cases during the same period. And in Brazil the proportion rose from just 1% in 1984 to 25% ten years later.

Furthermore, in the worst-affected countries, the virus is spreading fastest among young people below the age of 24 years -- at the peak of fertility. And in places where the virus is spread predominantly through heterosexual intercourse -- notably sub-Saharan Africa -- young women outnumber young men among those becoming infected. Studies sponsored by UNAIDS show that in western Kenya nearly one girl in four between the ages of 15 and 19 years is living with HIV compared with one in 25 boys in the same age group. In Zambia in this age range, sixteen times as many girls as boys are infected. And in rural Uganda among 20-24 year olds, there are six young women who are HIV positive for every infected young man. It is these high rates of infection, coupled with high rates of pregnancy among women, that explain

why, at the present time, Africa is also home to the vast majority of HIV-positive children.

Q: What is the risk that a baby born to an HIV-positive mother will acquire the virus from her?

The virus may be transmitted during pregnancy, childbirth, or breastfeeding. Where no preventive measures are taken, the risk of a baby acquiring the virus from an infected mother ranges from 15% to 25% in industrialized countries (most estimates are below 20%), and from 25% to 45% in developing countries (most estimates are between 30% and 35%). Evidence suggests that the risk of transmission is increased when the mother has a higher viral load (this is the case when a person is newly infected with HIV or is in an advanced stage of disease), or if the baby is highly exposed to the mother's infected body fluids during birth.

The difference in risk between developing and developed countries is due largely to feeding practices: breastfeeding is more common and usually practised for a longer period in developing countries than in the industrialized world. It is estimated that a child born uninfected to an HIV-positive mother has a one in five chance of acquiring the virus from her milk if it is breastfed. In places where breastfeeding is the norm, this route may account for more than one-third of mother-to-child transmissions of the virus.

Q: Shouldn't HIV-positive mothers be told not to breastfeed, if alternative feeding is available?

There are many reasons why such advice may not necessarily be appropriate -- and might, indeed, be dangerous. The cost of infant formula is often beyond the means of poor families in developing countries, even when it is widely available. Besides, many lack easy access to the knowledge, safe water and fuel needed to prepare replacement feeds safely, or simply have no time to prepare them. If used incorrectly -- mixed with unsafe unboiled water, for example, or over-diluted -- a breastmilk substitute can cause infections, malnutrition and even death. But even if a mother has the means to feed her baby safely with a breastmilk substitute, she may face other dilemmas. In cultures where breastfeeding is the norm, the very fact that she chooses not to breastfeed may draw attention to her HIV status and invite discrimination or even violence and abandonment by her family and community.

A further consideration is that breastfeeding suppresses ovulation and delays the return of a woman's fertility. A mother who does not breastfeed loses the natural contraceptive effect of the practice and is at increased risk of getting pregnant again too soon.

In August 1997, WHO, UNICEF and UNAIDS issued a joint Policy Statement on HIV and infant feeding. They subsequently prepared guidelines to help

national authorities to implement the policy. These documents emphasize that it is the individual mother's right to decide how she will feed her child; any attempt to influence her decision, no matter what the circumstances or motives, is an abuse of her human rights and freedom of choice. The responsibility of health or social work professionals who counsel HIV-positive women about infant feeding is to give them the fullest available information on the risks associated with breastfeeding, to discuss the feasibility and pros and cons of this and alternative feeding methods in the light of personal circumstances, and to give them appropriate support for the course of action they choose. And women should have easy access to voluntary and confidential counselling and testing for HIV. Since the majority of pregnant and lactating women attending clinics are likely to be HIV negative, information on how to protect themselves from infection is also a vital component of routine care.

Breastfeeding has been the cornerstone of child health and survival strategies for the past two decades and has played a pivotal role in reducing infant mortality in many countries. Even in the era of AIDS, breastfeeding remains the best possible nutrition for the great majority of babies and it is important that the practice by women who are HIV-negative or whose HIV status is unknown continues actively to be promoted, protected and supported.

Q: Shouldn't HIV-positive women be encouraged not to have children?

As with the issue of infant feeding, it is every woman's fundamental right -- as enshrined in human rights conventions -- to decide for herself, without coercion, whether or not to have children. The responsibility of the government and health services is to provide HIV-positive women and their partners with comprehensive information and education about the risks associated with childbearing as part of routine public information about HIV/AIDS, to ensure they have real choices of action, and to respect and support the decisions they reach. This means providing good quality, user-friendly and easily accessible family planning services so that HIV-positive women can avoid pregnancy if they choose, and similarly acceptable and accessible abortion services, where the procedure is legal, so that they can terminate pregnancy if desired.

For women to make informed decisions about childbearing in the AIDS era, they need to know and understand the implications of their HIV status. It is important, therefore, that voluntary and confidential counselling and HIV testing be widely available, and that its use by women, and their partners if desired, be promoted.

It should be recognized, however, that no matter how good the information, counselling and services a woman has access to, the decision about whether or not to have a child may still present her with agonizing dilemmas. In many parts of the world bearing children is of paramount importance, and may be a woman's only path to social status and self-fulfilment. Failure to get pregnant,

especially if she has no children already, will be noticed and commented on and may even be reason for abandonment by her partner. And if prejudice against people with HIV/AIDS is strong -- as it still is in many societies -- she may also risk her personal safety by raising suspicion that she is infected.

Q: What can be done to prevent babies from acquiring HIV from their infected mothers?

There are three complementary strategies for preventing mother-to-child transmission of HIV. They are:

- *The protection of girls and women from HIV infection*. This will minimize the risk that women of childbearing age are carrying the virus in the first place. The strategy is sometimes referred to as "primary prevention". It involves promoting safe and responsible sexual behaviour in couples, providing them with knowledge about HIV/AIDS and how to prevent infection, and ensuring that they have the necessary personal skills and access to condoms so that they can act on their knowledge. It also means providing good quality, user-friendly prevention and treatment programmes for other sexually transmitted diseases (STDs), the presence of which increases the risk of HIV transmission as much as 6-10 fold. And, crucially, it means taking steps to deal with the cultural, legal and economic factors that make girls and women specially vulnerable to HIV infection by limiting their autonomy and power to protect themselves.

- *The provision of efficient and accessible family planning services -- and abortion where this is legal -- to enable women to avoid unwanted pregnancies and births.* The aim is to ensure informed reproductive choice.

- *An integrated package of measures consisting of voluntary HIV counselling and testing (VCT), the provision of antiretroviral drugs for HIV-positive pregnant women (and sometimes their babies), counselling on infant feeding, and support for the feeding method(s) chosen by the mother.* This package is often referred to as the antiretroviral drug strategy.

In cases where a mother knows she is HIV positive and gives birth without the benefit of antiretroviral drugs during pregnancy or delivery, she can still refrain from breastfeeding, counting on the two-to-one chance that her baby has avoided infection in the womb or during childbirth. But if she chooses this course of action she should be made aware of the fact that she will lose the natural contraceptive effect of breastfeeding and be at increased risk of becoming pregnant again unless she takes alternative precautions.

Q: How can antiretroviral drugs be used to prevent mother-to-child transmission of HIV?

Until recently primary prevention measures and the provision of family planning were virtually the only options for limiting the number of HIV-infected children. However, in 1994, researchers in France and the United States reported the results of a major collaborative study, code-named ACTG 076, on mother-to-child transmission of HIV that offers a complementary strategy for HIV-positive women who want to give birth. The scientists found that when the antiretroviral drug zidovudine (AZT, or ZDV) is given to HIV-positive women orally five times daily from the 14th week of pregnancy onwards, and intravenously during labour, and administered to their infants for six weeks after birth, the risk of transmitting HIV from mother to child is reduced by over two-thirds if breastfeeding is strictly avoided. The ACTG 076 regimen is now offered routinely to HIV-positive women in the industrialized world and rates of MTCT below 5% are now common. However, the regimen is costly (approximately US$ 1000 per mother and child pair), long and complicated to administer, which means it is unsuitable for widespread use in developing countries.

Early in 1998, trials in Thailand sponsored by the country's Ministry of Public Health and the US Centers for Disease Control and Prevention showed that a shorter and simpler course of AZT is able to cut the rate of mother-to-child transmission of HIV by at least half if the baby is not breastfed. The infection rate was just above 9%, compared with a rate of 19% for babies of infected mothers who did not take antiretrovirals, but who also avoided breastfeeding. In this regimen, the drug is given to the mother only and consists of 300 mg of AZT taken by mouth twice daily from the 36th week of pregnancy and during labour.

UNAIDS stresses that an antiretroviral drug programme for the prevention of MTCT should never be adopted as an alternative to the other two strategies for protecting children from HIV, but as an addition. Everywhere, protecting girls and women from HIV infection and ensuring informed reproductive choice through good-quality and accessible family planning services, and abortion where legal, should remain high priorities.

Q: What happens if a mother who has taken the recommended course of antiretroviral drugs during pregnancy and delivery does breastfeed her baby after all?

This is a critically important question since the majority of HIV-positive women who risk transmitting the virus to their infants come from cultures where breastfeeding is the norm, and where artificial feeding often presents great difficulties.

Preliminary results from a number of ongoing studies in breastfeeding populations indicate that a short course of antiretrovirals can still reduce the transmission of HIV from the mother to the baby, though not as well as when mothers do not breastfeed. One of these studies is the PETRA trial, which is testing the effectiveness of a number of antiretroviral regimens using two drugs – AZT and lamivudine (3TC) – in combination. Coordinated by the UNAIDS Secretariat, this trial is being conducted in five urban settings in South Africa, Tanzania and Uganda. It is the largest-ever clinical trial to examine this issue. According to preliminary findings announced in February 1999, when an HIV-positive mother starts taking the two drugs at the time of delivery, and she and her newborn baby continue on the drug regimen for just one week following birth, the risk of the baby becoming infected is reduced to about 11% when measured at 6 weeks of age, as compared with a 17% risk when no antiretroviral drugs at all are given. An even bigger reduction – to 9% -- is seen when the drug regimen is started at 36 weeks of pregnancy, around a month before delivery. All mothers and babies involved in the trial will be followed for 18 months (to the middle of the year 2000), by which time the risks associated with breastfeeding under these conditions will be clearer.

Results from two other studies, conducted between 1995 and 1998 in Abidjan, Côte d'Ivoire, and Bobo-Dioulasso, Burkina Faso, were released in March 1999. It was found that the rate of HIV infection among breastfed babies whose HIV-infected mothers had a one-month course of AZT was about 18% at age 6 months (16% at age 3 months), compared with 27.5% (25% at 3 months) among babies whose mothers received no antiretrovirals. Again, research is being pursued to see whether the preventive effects of the antiretrovirals will be maintained to any significant degree if the babies continue to breastfeed beyond the age of 6 months.

In July 1999, the US National Institutes of Health released the results of a joint Uganda-US study comparing the preventive efficacy of a single dose of the antiretroviral drug nevirapine, given to the mother during labour and to the baby within the first three days of life, with that of AZT given in labour to the mother and administered to the baby for one week after delivery. Measured at around 3 months of age, HIV infection was found in 25% of the infants who received AZT, compared with 13% in those receiving nevirapine. Again, the infants will be followed up until they are 18 months old to understand the impact of breastfeeding on this reduced transmission rate.

In the meantime, it is a point of principle that an HIV-positive woman's ability and willingness to give her child a breastmilk substitute should not be a precondition for offering her antiretroviral drugs for the prevention of MTCT if they are available in the health system. HIV-positive mothers who choose to breastfeed should be supported in their decision, and they should be advised that giving breastmilk exclusively for the duration of breastfeeding, stopping the practice as early as possible, and taking care to avoid cracked nipples and breast abscesses will all help to reduce the risk of transmitting the virus.

THE VARIABLE RISK OF MTCT

In summary, the rates of mother-to-child transmission of HIV under the different regimens and circumstances are as follows:

*** Where no drugs are administered and the baby is breastfed by its HIV-positive mother, the risk of infection is generally around 30-35%.**
*** Where no drugs are administered and the baby is not breastfed by its HIV-positive mother, the risk of infection is around 20%.**
*** Where a one-month course of AZT is administered and the baby is not breastfed, the risk of infection is around 10%.**
*** Where a one-month course of AZT is administered, and the baby is breastfed by its HIV-positive mother for up to 6 months, the risk of infection is about 18% at that age, according to preliminary data.**
*** Where two antiretrovirals, AZT and 3TC, are administered at the time of labour, and to mother and baby for one week following delivery, the risk of infection at 6 weeks of life, with breastfeeding, is around 11%. If the drugs are given from the 36th week of pregnancy, continued in labour and given for a further week after delivery, the risk of infection at 6 weeks of life, when the baby is breastfed, is around 9%. The rates of infection with continued breastfeeding will only be known when the data from follow-up of the PETRA trial are complete.**
*** Where one oral dose of nevirapine is given to the mother in labour and to the baby within three days of birth, the risk of infection at 3 months of life is about 13%, with breastfeeding. The risk at later ages, in infants that continue to breastfeed, will be determined through follow-up.**

Q: What effect do the antiretroviral drugs have on the mother?

A short course of AZT during pregnancy and delivery (and possibly the early post-partum period), while dramatically increasing the chance that she will give birth to an uninfected baby, does no harm to the health of an HIV-positive woman. The only possible risk is anaemia. But any pregnant woman taking antiretrovirals for HIV will be doing so under the supervision of the maternal health services, where screening for anaemia and treatment for the condition if necessary should be routine procedures.

Taking AZT alone, which is the currently recommended regimen for MTCT prevention, is now recognized to offer no intrinsic long-term therapeutic benefits for HIV-infected people who have not yet developed symptoms of

HIV-related illness. Only HIV-positive women who have progressed to the end-stage of illness called AIDS could hope to improve their quality of life and extend it by a few months by pursuing monotherapy with AZT.

However, all women, whether or not infected with HIV, stand to benefit considerably from the high quality of maternity care and other services that are the necessary foundation for the introduction of such an antiretroviral drug programme.

Q: Isn't there a danger of drug resistance developing?

The risk of developing drug-resistant strains of HIV is considered to be minimal when antiretrovirals are used for a short period of time. Research and extensive experience with AZT, which has been in clinical use since 1987, indicates that the virus takes at least three months to develop resistance to the drug when used as monotherapy. On the other hand, HIV has been shown to develop resistance to nevirapine monotherapy very quickly. Since only a single dose of nevirapine has been given to mother and baby in the study of MTCT prevention, resistance is not expected to be a problem, but no data are yet available to confirm this.

If antiretroviral drugs are used in combination, resistance is even slower to develop than with monotherapy as they offer the virus a more complex challenge. At present, however, the risk of developing drug resistance if a woman is treated with the same drug over several pregnancies is not known.

Q: Can antiretroviral regimens like this harm the baby?

Two French infants born to mothers who had taken antiretrovirals during pregnancy died in 1998 from a rare neurological condition caused by mitochondrial disease (mitochondria, found in all cells, are essential for normal cell function). This prompted a search of the records of around 5000 other children born to HIV-infected mothers in France. No deaths were found, although six living children showed signs that could be caused by mitochondrial disease. Elsewhere in the industrialized world, no causal relationship has been identified between infant or child death and antiretroviral drugs given during pregnancy. Nor has any evidence of mitochondrial disease been found among the 1800 mother-child pairs recruited for the PETRA trial. This issue will continue to be looked at carefully during follow-up in both developing and developed countries.

Overall, the consensus is that the beneficial effect of antiretrovirals given for MTCT prevention - a significant reduction in the baby's risk of infection with a fatal virus -- far outweighs any risk to the infant.

Q: What are the preconditions for adopting the antiretroviral strategy for the prevention of mother-to-child transmission of HIV in a given city, district or country?

For women to take advantage of measures to protect their offspring from infection they need to know and accept their HIV status. Voluntary and confidential counselling and testing services therefore need to be widely available and acceptable before the drug strategy is introduced. Pregnant women must have ready access to antenatal and postnatal care and be able to give birth in a maternity ward or clinic with professional assistance, since skilled supervision of the drug regimen is necessary. In addition, expert counselling on infant nutrition and safe alternatives to breastfeeding must be available to all. Other health system prerequisites for introducing the strategy are efficient systems of quality control, supply and distribution of antiretroviral drugs and HIV test kits, and laboratory facilities with adequate capacity and skills.

In addition, women's personal safety must be assured. The administration of drugs and avoidance of breastfeeding make it virtually impossible for HIV-positive women to keep their infection secret from their families and people in the wider community. Thus, if there is prejudice in society against people with AIDS that might put women identified as HIV positive at risk of rejection or violence, this must be overcome before the drug strategy is widely introduced.

Overcoming the shame and rejection associated with AIDS is an enormous challenge. Stigma remains widespread, even in communities where a tenth or more of the adult population is HIV infected. The health-service challenges are equally daunting. At present, some 40% of the world's women lack access to adequate antenatal care. In sub-Saharan Africa, less than half of all births are attended by professional health staff, with proportions well below this being reported from individual African countries as well as from parts of Asia. The proportion of people without access to health care at all ranges from over 40% in some parts of Latin America and Asia, to nearly 80% in the poorest parts of Africa. Moreover, for huge numbers of mothers in the developing world, there is no truly safe alternative to breastfeeding even if infant formula is available, for they lack access to the clean water, fuel and knowledge needed to prepare it properly.

Q: Aren't the costs of the antiretroviral drug strategy prohibitive for developing countries?

The affordability of an antiretroviral drug programme for preventing MTCT will depend a great deal on the condition of the health infrastructure within a country or district, and how much strengthening or expansion of services is needed before the strategy can be introduced. Generally speaking, antiretroviral drugs for mothers known to be HIV-positive and breastmilk substitutes for their babies are affordable in most countries, or districts within countries, where there are already well-functioning health care systems.

In Thailand, where the effectiveness of a one-month course of AZT together with replacement feeding was first demonstrated, the cost of antiretroviral drugs was US$ 50 per woman. Taking this as the baseline cost for drugs, and a realistic estimate of US$ 50 per child for a six-month supply of infant formula, the cost of the strategy for one mother-and-child pair would be approximately US$ 130, including the costs of counselling and other inputs.

But what does this figure mean from the point of view of the national health budget? If one takes a hypothetical country with a birth rate of 40 per 1000 and a 15% HIV prevalence rate among pregnant women, and one assumes that all women who know they are seropositive (typically around 10% of those infected) accept the intervention, the cost *per capita* would amount to around US$ 0.08. This calculation does not take into account savings of medical and other expenditures to care for HIV-positive infants -- which, though admittedly very low in some countries, can be substantial in others.

The much shorter antiretroviral regimens being tested in the ongoing PETRA and Uganda nevirapine trials are likely to be even cheaper than the currently recommended one-month course of AZT. As a result the total cost of providing antiretrovirals may be reduced, and it may become more cost-effective to introduce the intervention in very-low-income countries.

Voluntary counselling and testing also needs to be taken into consideration. If the cost of this service is to be borne exclusively by MTCT prevention programmes, the cost-effectiveness of the strategy will depend on the HIV prevalence in the area: the higher the prevalence, the less it will cost to identify each HIV-positive pregnant woman.

Where HIV prevalence is high, the cost of a programme of voluntary counselling and testing, AZT and replacement feeding compares well with the cost of interventions for other health problems. It is estimated, for example, that at HIV prevalence rates of 5% and above, this strategy costs around US$ 35 per Disability-Adjusted Life Year (DALY)[1], compared with US$ 20-40 per DALY for polio and diphtheria vaccination, and US$ 200-400 per DALY for river blindness prevention. However, where HIV prevalence is low in the general population, the cost-effectiveness of the intervention is also lower. Under these circumstances, it may be better to focus only on population groups with particularly high prevalence rates, offering HIV testing to the women who are pregnant or planning a pregnancy.

[1] Disability-adjusted life years (DALYs) are the number of years of life saved through a particular intervention, discounted slightly for each successive year saved to take account of the fact that the quality of life diminshes as time passes and the risk of dying of some other disease increases. Thus, the first year of life saved as the consequence of the intervention counts as a full year, whereas each successive year counts for a little less each time. The great strength of DALYs is that they reflect both quality of life and chances of survival, and allow for easy comparison between different kinds of intervention.

Whatever the circumstances, the cost of antiretroviral programmes is a major consideration in developing countries, and UNAIDS and its partners regularly engage in negotiations with industry to try to secure more affordable prices for drugs as well as HIV test kits and infant formula. In March 1998, Glaxo Wellcome announced preferential prices for AZT for the prevention of mother-to-child transmission in developing countries. HIV test kits can be purchased at low prices through the supply division of WHO, and low-cost generic infant formula through UNICEF's supply division. In addition, UNAIDS is collaborating with various partners to document case studies and draw lessons from countries which have managed to provide antiretroviral drugs for MTCT despite scarce resources.

Q: Does the antiretroviral drug strategy for the prevention of mother-to-child transmission of HIV have any wider benefits?

Providing voluntary counselling and testing, antiretroviral drugs and replacement feeding for the reduction of MTCT has benefits that extend way beyond the direct benefits to the health and survival of infants. All pregnant women, mothers and infants will benefit from the expanded provision and improved quality of health care, especially mother-and-child health, antenatal, delivery and postnatal services. And the population as a whole will benefit from general strengthening of the health infrastructure, as well as from the increased understanding and acceptance of the AIDS epidemic and those affected that develop as a consequence of counsellling and testing and measures taken to combat stigmatization. A decision to introduce the strategy can, in the first place, be a force for social change, providing the opportunity and impetus needed to tackle often long-standing problems of inadequate services and oppressive attitudes.

Q: What are the benefits of voluntary and confidential HIV counselling and testing for the population in general?

For pregnant women to take advantage of measures to protect their offspring from HIV infection they need to know whether or not they are infected. So voluntary counselling and testing services are an essential part of any programme for the prevention of mother-to-child transmission of HIV. Ideally, however, everyone should have access to such services since there are clear advantages to knowing one's serostatus. People who know they are HIV infected are likely to be motivated to look after their health, perhaps with behaviour and lifestyle changes, and to seek early medical attention for problems. They can make informed decisions about sexual practices, childbearing, and infant feeding, and take steps to protect partners who may still be uninfected. And those whose test results are negative can be counselled about how to protect themselves, their partners and their children from infection.

Furthermore, voluntary counselling and testing has an important role to play in unmasking the silent epidemic and reducing the hysteria and fear surrounding AIDS. At present, UNAIDS estimates that around 90% of people with HIV are unaware of their status. Efficient, widely accessible and user-friendly testing services can help societies recognize and come to terms with the fact that there are many people living with HIV who show no outward signs. This in turn encourages commitment to prevention.

It is still common for women to be blamed for spreading sexually transmitted diseases, including HIV, despite the fact that very often they are infected by the husband or partner to whom they are entirely faithful. Voluntary counselling and testing that involves the partners of pregnant women, where this is feasible and desired, can play a vital part in challenging this pervasive prejudice.

In 1997 UNAIDS issued a policy statement on HIV counselling and testing which endorses the value of this service as a critical part of an effective response to HIV/AIDS, and sets down the guiding principles. UNAIDS promotes the establishment of voluntary counselling and testing services, offers technical assistance, and is currently supporting pilot projects in selected countries to find out how such services can be made as effective, efficient and acceptable as possible to those who wish to know their status.

Q: Aren't there ethical issues involved in the use of antiretroviral drugs for the prevention of mother-to-child transmission of HIV?

The ethical implications of the strategy are given very serious consideration. A guiding principle, whenever these measures are made available to reduce MTCT, is that it is the pregnant woman's absolute right to choose, on the basis of full information, whether or not to take advantage of the intervention. Coercion is not justified under any circumstances, even if it seems to be in the best interests of the woman or her child, and her choice should always be accepted and respected. Thus, where it is available, an antiretroviral drug programme will give HIV-positive mothers the possibility, at their own discretion, of protecting their babies from infection -- a chance they would otherwise not have.

However, introducing antiretroviral drug programmes for the prevention of mother-to-child transmission in countries where antiretrovirals are not available for the treatment of HIV-positive people more generally has raised sometimes heated debate. The question is asked: If a mother's access to antiretroviral drugs is limited to the period of pregnancy and labour, does this amount to treating the mother for the sake of her baby alone? In fact, the question is based on an erroneous perception, for an antiretroviral drug used for this purpose is not really a treatment, but a "vaccine" for the infant. A useful analogy is the rubella vaccine given to pregnant women to protect their offspring from the ill-effects of maternal infection. Rubella vaccination does not meet with ethical objections, despite the fact that it, too, could be seen as treating the mother for the sake of the baby.

The fact that antiretrovirals can serve two separate purposes -- as vaccine for infants against mother-to-child transmission of HIV, and treatment for HIV-infected individuals -- is, of course, very significant. But the issue of antiretroviral treatment for infected people must be considered separately from the issue of antiretroviral drugs used for the prevention of mother-to-child transmission. It requires debate and policy decisions outside the scope of MTCT policy-making.

It is important also to remember that a short course of antiretrovirals during pregnancy, while increasing the chance that she will give birth to an uninfected baby, does no harm to the health of an HIV-positive woman. Moreover, it is a point of principle when adopting a strategy of antiretroviral drug use that HIV-positive pregnant women must be assured of the best possible care available in their countries. In some places antiretroviral drugs will be available for therapy, too; in others, such treatment will simply not be feasible.

Q: Won't this strategy exacerbate the problem of orphaned children?

The idea that introducing the antiretroviral drug strategy for the prevention of MTCT might exacerbate the problem of orphaned children and increase the burden on families and societies is based largely on the assumption that children born to HIV-infected mothers do not survive long enough to become orphans. But this is a misconception. In the absence of preventive measures for pregnant HIV-infected women, around 65% of the children born to them will escape infection but face orphanhood; of those who are infected (35%), many will likewise survive longer than their mother. With the prevention strategy, the percentage of uninfected prospective orphans will rise to almost 90% but in parallel there will be a significant decrease – two- to three-fold – in the number of infected orphans. Thus, with or without the intervention, the great majority of the babies born to HIV-infected mothers will be exposed to the risk of being orphaned.

The intervention does not therefore affect in any significant way the need for societies to make provision for their orphaned children. However, from the point of view of planning for care and allocating resources, it is important to recognize that, in the absence of measures to reduce mother-to-child transmission, many more orphaned children will be HIV infected and will require medical care as well as support, many of them long-term. It is also worth noting that the strategy is likely to spare many HIV-positive mothers who may be struggling with their own ill-health the stress and misery of caring for sickly infants.

Q: The prevention of mother-to-child transmission of HIV is one of UNAIDS' top priorities -- so is the Programme advocating that the antiretroviral drug strategy should be introduced everywhere? [2]

UNAIDS believes that the prevention of mother-to-child transmission of HIV should be given high priority in all countries. Measures to protect girls and women from becoming infected in the first place, and to allow those women who are HIV positive to avoid pregnancy or birth if they so wish, should be part and parcel of every national AIDS programme. However, the issue of whether or not to introduce the antiretroviral drug strategy for the prevention of MTCT is more complex. Wherever suitable conditions exist already, UNAIDS recommends that the strategy -- consisting of voluntary counselling and testing for HIV, provision of antiretroviral drugs, counselling on infant feeding and support for the mother's chosen feeding methods -- should be introduced without delay. But where there is uncertainty about the political will to introduce these measures, the acceptability of the intervention, the availability of resources, the strength of the existing health infrastructure to take on and to sustain the added burden of the service, and -- crucially -- where there is evidence of persecution of individuals who are infected, UNAIDS recommends that the strategy be tested thoroughly in pilot sites before being considered for wider introduction in a country. In yet other places, where such an intervention would clearly be beyond the capability of the health

[2] *See*: "Prevention of HIV Transmission from Mother to Child: Strategic options", UNAIDS, May 1999, available through UNAIDS Information Centre or the Programme's web site (www.unaids.org)

infrastructure, that infrastructure would need to be strengthened even before pilot projects are begun.

Q: What specifically is the purpose of pilot-testing?

The purpose of pilot-testing the strategy is to make sure it is feasible, safe, sustainable, and acceptable to the general public before it is introduced more widely in a country, and to learn lessons about how best to operate the new services.

Safety of the mother is a prime consideration. Women who take special drugs during pregnancy and then avoid breastfeeding can scarcely keep their HIV infection secret from their family and community. In places where stigmatization of HIV-infected people is a serious problem, pilot-testing of the antiretroviral strategy is essential so that the risks associated with stigma can be measured in a carefully supervised setting and ways of reducing them investigated. No programme to prevent MTCT can operate safely or effectively in a climate of fear, and oppressive attitudes and behaviour towards people with HIV have to be tackled directly.

Replacement feeding raises serious safety issues for the infant. In places where infectious diseases and malnutrition are primary causes of infant death, replacement feeding typically plays a major role. In some studies it has been associated with a 1.5-5 fold increase in the risk of death. Unless mothers have the relevant knowledge, as well as easy access to infant formula they can afford and to clean water and fuel for sterilizing water and implements, replacement feeding is not safe. Pilot sites are the places to monitor the risks associated with replacement feeding in a particular setting, and to investigate ways of meeting the conditions for safe practice.

Experience to date in many countries shows that there is great variation in willingness to make use of voluntary counselling and testing services for HIV even where they are widely accessible. For example, a significant proportion of women who accept an HIV test during antenatal care fail to return for the results. The fear of stigma and discrimination if they test positive undoubtedly deters people -- and has proved all too tragically realistic in a number of cases, where infected people have been rejected and even killed by their communities. However, this is only part of the picture and where HIV testing services are underutilized, pilot studies are needed to identify the full range of factors that influence decisions to take an HIV test and what is needed to overcome resistance.

Measures introduced for the prevention of MTCT are intended to be fully integrated with the wider programme for HIV/AIDS prevention and care in a country. Therefore, a pilot project should only be set up where a range of care facilities already exists to which women can be referred if they test HIV

positive. Already, pilot projects are in various stages of planning and implementation in all regions of the developing world.

Q: What is the role of UNAIDS regarding mother-to-child transmission of HIV?

The prevention of mother-to-child transmission of HIV has been a priority for UNAIDS ever since its creation in 1996, and it has played a key role in establishing the extent of the problem, in finding ways to reduce it, and in mobilizing action at international and national level.

The Programme helps identify issues for research and provides coordination and/or financial support. For example:

- coordinated by the UNAIDS Secretariat, the PETRA study is looking at the efficacy of alternative short drug regimens for prevention of mother-to-child transmission of HIV, especially in breastfeeding populations;
- the International Working Group on Clinical Trials, also coordinated by the UNAIDS Secretariat, meets twice a year to review results and discuss future trials;
- the Secretariat provides financial support for coordination and for selected research carried out by the Ghent Group (studying *inter alia* the acceptability of voluntary counselling and testing, risks associated with breastfeeding, and the care of children with HIV/AIDS) and by the NARESA Group of HIV/AIDS researchers from East and southern Africa (studying mother-to-child transmission of the virus, among a range of issues).

In addition, the UNAIDS Secretariat and the Cosponsors -- in particular UNICEF, UNFPA and WHO -- are currently supporting pilot projects for the prevention of mother-to-child transmission in 11 countries in Africa, Asia and Latin America where women have high rates of HIV infection. The pilot programme aims eventually to provide VCT for 100,000 women, and support for approximately 30,000 women who are HIV positive, in 30 sites in these countries. UNAIDS is also committed to assisting countries in their efforts to scale up the service and introduce voluntary counselling and testing, antiretroviral drugs, and replacement feeding more widely in due course.

The initiative for these activities came out of a meeting convened by the UNAIDS Secretariat in March 1998, following the release of the results from the Thailand trials which showed that a simplified regimen of antiretroviral drugs could reduce the risk of mother-to-child transmission of HIV by half. The meeting -- organized in collaboration with UNAIDS Cosponsors and attended by representatives of national health authorities, development agencies and research institutes -- called for immediate international action to prevent mother-to-child transmission of HIV and discussed ways of facilitating the introduction of programmes in countries. An Inter-Agency Task Group on Prevention of Mother-to-Child Transmission was set up with the aim of giving

strong and coordinated leadership and guidance on this issue. The Task Group focuses on communicating up-to-date technical information to countries through meetings, documents and the internet (*see annex)*; on providing advice and assistance with strategic planning for MTCT prevention activities; and on helping countries overcome obstacles to the introduction of the antiretroviral drug strategy.

In addition to these activities, UNAIDS continues to advocate for concerted action to prevent mother-to-child transmission of HIV by all means available, to mobilize and coordinate the international effort, and to look for ways of making the available strategies as affordable and feasible as possible for the countries that most need them.

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ANNEX

List of documents on MTCT available through UNAIDS Information Centre or through UNAIDS web site (www.unaids.org):

General Information:

- HIV Transmission from Mother to Child UNAIDS Technical Update (October 1998)
- Prevention of HIV Transmission from Mother to Child : Planning for Programme Implementation. Report from a Meeting, Geneva, 23-24 March 1998, UNAIDS Key Material, 1998
- Prevention of HIV Transmission from Mother to Child: Strategic options, UNAIDS (May 1999)
- AIDS 5 years since ICPD: Emerging issues and challenges for women, young people and infants, UNAIDS (1999)

HIV Counselling and Testing:

- Counselling and voluntary HIV testing for pregnant women in high HIV prevalence countries: Guidance for service providers, UNAIDS (May 1999)
- The importance of simple/rapid assays in HIV testing. WHO/UNAIDS recommendations. *Weekly Epidemiological Record* 1998, **73**, 321-328

Antiretroviral treatments:

- WHO/UNAIDS recommendations on the safe and effective use of short-course ZDV for prevention of mother-to-child transmission of HIV. *Weekly Epidemiological Record* 1998, **73**,313-320
- The use of antiretroviral drugs to reduce mother to child transmission of HIV (module 6). Nine guidance modules on antiretroviral treatments, WHO/UNAIDS, 1998 (UNAIDS/98.7)

HIV and Infant Feeding:

- HIV and Infant Feeding: A review of HIV transmission through breastfeeding, WHO/UNAIDS/UNICEF, 1998 (UNAIDS/98.5)
- HIV and Infant Feeding: Guidelines for decision-makers, WHO/UNAIDS/UNICEF, 1998 (UNAIDS/98.3)
- HIV and Infant Feeding: A guide for health care managers and supervisors, WHO/UNAIDS/UNICEF, 1998 (UNAIDS/98.4)
- WHO/UNAIDS/UNICEF, Technical Consultation on HIV and Infant Feeding Implementation guidelines. Report from a meeting, Geneva 20-22 April 1998.
- HIV and Infant Feeding: a UNAIDS/ UNICEF/WHO policy statement (May 1997)

Planning, Implementation and Monitoring&Evaluation:

- Vertical Transmission of HIV - A Rapid Assessment Guide (1998)

- Local Monitoring and Evaluation of the Integrated Prevention of Mother to Child HIV Transmission in Low-income Countries (1999)

MTCT prevention in Asia:

- Thaineua V et al. From research to practice: Use of short-course zidovudine to prevent mother-to-child HIV transmission in the context of routine health care in Northern Thailand, *South East Asian Journal of Tropical Medecine and Public Health*, 1998.

MTCT prevention in Latin America:

- Prevention of vertical transmission of HIV. Report from a workshop, Buenos Aires 29-31 July 1998.

MTCT prevention in Africa:

- The Zimbabwe Mother-to-Child HIV Transmission Prevention Project: Situation Analysis